



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SP 00P-0117/CP 1

MAR 9 2000

Robert D. Gunderson
Phoenix Scientific, Inc.
3915 S. 48th St. Terrace
P.O. Box 8039 (64508)
St. Joseph, MO 64503

Dear Mr. Gunderson:

We refer to your suitability petition dated December 30, 1999, and filed January 10, 2000, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a lincomycin/spectinomycin water-soluble powder.

The pioneer product, NADA 46-109, is Pharmacia & Upjohn's LS 50 Water-Soluble® Powder (lincomycin hydrochloride monohydrate/ spectinomycin sulfate tetrahydrate), and is administered orally to chickens in the drinking water. Your proposed generic product is lincomycin hydrochloride monohydrate/ spectinomycin dihydrochloride pentahydrate. Spectinomycin dihydrochloride pentahydrate is approved as a single active ingredient product for chickens (NADA 38-661), as Spectam® Water-Soluble Concentrate. Therefore, your generic product is a substitution of one approved salt for another in a combination product.

After careful consideration, we are approving your suitability petition. Substitution of one active ingredient in a combination product is one of the allowable differences between the pioneer and generic products which may be considered in a suitability petition, as provided by section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended. We are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed generic product.

Approval of the suitability petition allows you to submit an ANADA for the requested variation from the pioneer product, but does not alter the requirements for approval of the ANADA, nor assure approval of the ANADA. The requirements for approval of your proposed generic product include a study to demonstrate the bioequivalence of your product and the pioneer product, LS 50, as required by Section 512(n)(1)(B)(ii) of the FFDCA.

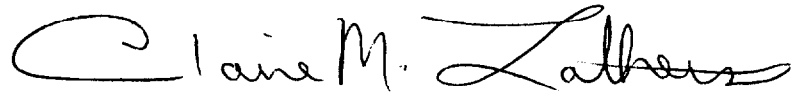
We will conduct a definitive labeling review when the ANADA for the proposed generic product is submitted to the Center. The generic labeling should be a verbatim copy of the approved labeling for the pioneer, with certain allowable differences, such as changes related to the different active ingredient.

00P-0117

PAVI

You may contact Dr. Lonnie W. Luther, Chief, Generic Animal Drug and Quality Assurance Staff, (301) 827-0209, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,

A handwritten signature in black ink, reading "Claire M. Lathers". The signature is fluid and cursive, with the first name "Claire" being the most prominent part.

Claire M. Lathers, Ph.D., F.C.P.

Director

Office of New Animal Drug Evaluation

Center for Veterinary Medicine

MEMO

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

3502 '00 MAR 10 AM 11:04

DATE: 3/10/00

FROM: Animal Scientist
Quality Assurance Support Staff, HFV-102

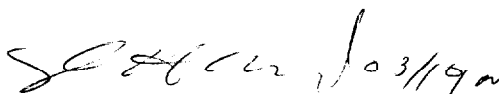
SUBJECT: Suitability Petition Response for Display.

TO: Lyle Jaffe, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD
Dockets Management Branch, 301 827-6860 (V)

The attachment is the Center for Veterinary Medicine's letter related to Suitability Petition **SP 00P-0117CP 1**, Phoenix Scientific filed as a **Suitability Petition**. We are forwarding a copy for public display with the petition.

If you have any questions, please call me at 827-0211, or FAX 594-2297.

Thank you.

A handwritten signature in black ink, appearing to read 'SHANSARD 3/10/00'.

Sam Hansard, Ph.D.

Attachment

Samuel Hansard, Ph.D.
FDA/CVM/ONADE/QASS/HFV-102
7500 Standish Place MPN II 384
Rockville, MD 20855
(301) 827-0211
(301) 594-2297 fax
shansard@cvm.fda.gov

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JANUARY 10, 2000

DOCKET NUMBER: 00P-0

TITLE: ANADA Suitability for Lincomycin-Spectinomycin Water Soluble
ACTION OFFICE: HFV-102

FAC/CLAP/GRASP Number:

ITEM CODE	RECEIVED MM DD YY	FILED MM DD YY	P C	SUBMITTER	FI DATE	FR PAGE	COM/OBJ MM DD YY	VOL	MISCELLANEOUS
CP1	01/06/00	01/10/00	C	Phoenix Scientific Inc Signature: Robert D Gunderson					1 ACK 1/10/00
ACK1	01/10/00	01/10/00	E	HFA-305 Signature: Jennie C Butler					1

3503 '00 MAR 10 AM 10:04

00P-0117

TO NORMA/Tan JAN 13 2000
DRAFT Htr JAN 13 2000